Innovations in Breast Cancer Drug Development – Next Generation Oncology Trials
Breast Cancer Workshop
October 21, 2014
Hyatt Regency Bethesda, Bethesda MD

Co-sponsored by the U.S. Food and Drug Administration, the American Association for Cancer Research, the American Society of Clinical Oncology and the Breast Cancer Research Foundation

Co-Chairs: Dr. José Baselga and Dr. Patricia Cortazar
Moderator: Dr. Clifford Hudis

AGENDA

8:00 – 8:20	**Next Generation Oncology Trials: Changing the Breast Cancer Drug Development Paradigm**	**Patricia Cortazar**
8:20 – 8:35	**What Can We Learn From Genomically-Driven Trials In Other Tumors?**	**Julia Beaver**
8:35 – 8:50	**How Can We Improve Targeted Drug Development For "Small" Populations With Genomic Alterations?**	**Martine Piccart**
8:50 – 9:30	**Panel Discussion:** ▪ **Academia:** o **What would make you interested in participating in such a trial?** o **What concerns do you have?** ▪ **Industry:** o **What would make you interested in participating in such a trial?** o **What concerns do you have?** ▪ **Advocates:** o **What would make the advocacy community endorse such a trial?** o **What concerns do you have?**	
9:30 – 9:35	Audience Questions/Comments	
9:35 – 9:45	Break	
9:45 – 9:55	**Why Do We Need To Combine Targeted Agents In Drug Development?**	**Larry Norton**
9:55 – 10:05	**How To Co-Develop Two New Agents?**	**Laleh Amiri**
10:05 – 10:20	**Which Molecular Pathways Are Worthwhile Targeting In Breast Cancer?**	**Charles Perou**
10:20 – 10:35	**How Can We Move Forward With Combination Targeted Therapies In A Breast Cancer Genomically-Driven Trial?**	**Nikhil Wagle**
10:35 – 11:35	**Panel Discussion:** ▪ **Discuss patient populations and pathways of interest for this trial** ▪ **Which pathways require targeting by multiple agents?** ▪ **What are the drug class combinations of interest for these pathways?** ▪ **What are the important strategies for selecting these targets?**	
11:35 – 11:40	Audience Questions/Comments	

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11:40 – 12:30	*Lunch*	
12:30 – 12:45	**How Can We Implement Strategies For A Breast Cancer Genomically-Driven Trial?**	**David Solit**
12:45 – 1:00	**What Is The Utility Of Liquid Biopsies In A Genomically-Driven Trial?**	**Victor Velculescu**
1:00 – 1:10	**What Are The Co-Diagnostic Regulatory Considerations For A Genomically-Driven Trial?**	**Elizabeth Mansfield**
1:10 – 2:10	**Panel Discussion:** ▪ **What genomics platform(s) should be used to screen for eligibility?** ▪ **What testing validation needs to occur (central vs. local)?** ▪ **Should liquid biopsy be incorporated both for initial enrollment and for tumor response?** ▪ **Should multiple biopsies be taken (different sites at screening or throughout the study)?**	
2:10 – 2:15	Audience Questions/Comments	
2:15 – 2:25	*Break*	
2:25 – 2:35	**What Are The Regulatory Considerations For Statistical Approaches In The Genomic Era?**	**Lisa LaVange**
2:35 – 2:45	**How Can We Optimize Data Collection In The Era Of Personalized Medicine?**	**Clifford Hudis**
2:45 – 3:30	**Panel Discussion:** ▪ **What is the optimal trial design?** ▪ **How can we optimize data collection and analysis?**	
3:30 – 3:35	Audience Questions/Comments	
3:35 – 3:55	**Wrap Up: Summary & Future Directions**	**José Baselga**
3:55 – 4:55	**Panel Discussion:** ▪ **How can a global trial targeting genomic alterations with low prevalence be implemented?** ▪ **What are the next steps?**	
4:55	Adjournment	

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